REMARKS

This amendment is in response to a non-final Office action (Paper No. 10) mailed 25 November 2003. Claims 8-13, 15-22, 24-29, 31-33, 35-50, and 53-70 are pending in this application. Applicant has amended claims 8, 65 and 70 by this amendment, and added claim 71 to alternatively define the invention disclosed. No new matter has been added.

I. Claim Objection

Claim 65 was objected to because of the informality.

Claim 65 has been amended to correct a typographical error.

II. Claim Rejections - 35 U.S.C. 101

The examiner asserted that claims 8-13, 15, 17, 29, 32, 58-64, 68 and 70 stand rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

MPEP 2107.01 states that:

> "[a]n invention that is "inoperative" (i.e., it does not operate to produce the results claimed by the patent applicant) is not a "useful" invention in the meaning of the patent law. See, e.g., *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); *In re Harwood*, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) ("An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. 101 that an invention be useful."). However, as the Federal Circuit has stated, "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An

> invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity." If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA), *reh'g denied*, 480 F.2d 879 (CCPA 1973); *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971)."

Here, the examiner asserted that Phillips '547 discloses that alkanes (saturated hydrocarbons) are the by-products of reactive oxygen species interactions and that unsaturated hydrocarbons are what are reactive with oxygen free radicals and that applicant's written description is devoid of how a compound that is already at its highest level of oxidation could be further oxidize to neutralize an oxygen free radical.

The examiner's reasoning is not proper. The term "oxidation" includes any reaction in which electrons are transferred. Phillips merely shows one of the reactions associated with the reactive oxygen species, but not show all the reactions associated with the reactive oxygen species. It is well known that the fact that alkanes can be oxidized by oxygen or reactive oxygen species. The fact that alkanes can be produced from the degradation of PUFAs does not mean that alkane itself cannot be oxidized by reactive oxygen species. Furthermore, one of the objects of the present invention is to combine with and overwhelm the reactive oxygen species, and to remove them as they are produced in order by greatly lowering the levels of these reactive oxygen species. That is, one of the objects of the present method is to removes the reactive oxygen species before the oxidative damages shown in Phillips occurs. For example, in Phillips, immediately after forming in the energy centers of the

mitochondria free radicals are subject to attack by the fuel gas. Accordingly, the more hydroxyl radicals and superoxide radical react with the fuel gas intentionally supplemented before PUFA is oxidized by reactive oxygen species. The effectiveness of the removal of the reactive oxygen species is a function of the amount of the fuel gas in solution. The applicant already stated in the specification that, even if methane exists naturally in the blood stream, the quantity is small and the low diffusivity of methane results in most of it leaving the body as flatus (as shown in Phillips). Accordingly, for example, in claim 8 of the present invention uses oxygen *intentionally supplemented with a fuel gas*. In claim 8, the reaction condition is not the same as Phillips, which does not use oxygen intentionally supplemented with a fuel gas. Furthermore, the examiner improperly regards Phillips '547, particularly Fig. 1, as all of the possible reactions from reactive oxygen species. Nonetheless, the examiner asserted that the present invention is inoperative because of the reactions shown in Phillips.

Therefore, Phillips is not the evidence showing that the reactive oxygen species cannot be further oxidized with the fuel gas such as methane, ethane, and propane.

With respect to the use of hydrogen, the examiner asserted that Phillips discloses that hydrogen is actually involved in the creation of oxygen free radicals and not the elimination of such and that Applicant's written description is devoid of how a compound that is involved in a reaction that creates an oxygen free radical, can help to protect tissue from oxygen free radicals.

The examiner misunderstood Phillips. It is well known that the reactive oxygen species are formed by different mechanisms such as the interaction of ionizing radiation with biological

molecules, an unavoidable byproduct of cellular respiration, and synthesis by dedicated enzymes in phagocyte cells like neutrophils and macrophages. Phillips shows the unavoidable byproduct of cellular respiration. As shown in Phillips, in aerobic organisms like humans, oxygen is converted to water at the end of the mitochondrial respiratory chain, but the reactive oxygen species may be generated when some of the electrons passing through the respiratory chain leak from the electro carriers and pass directly onto oxygen, reducing it to O_2. That is, some of the reactive oxygen species are formed upon one-electron reduction of oxygen from the respiratory chain as shown in Phillips. Actually, Fig. 1 of Phillips illustrates water and superoxide radical are produced from oxygen in the mitochondrial respiratory chain. Phillips does not disclose that hydrogen gas itself creates reactive oxygen species, does not show that the hydrogen gas does not eliminate the reactive oxygen species and only creates an oxygen free radical, and does not show that the higher level of the hydrogen gas than the background level does not eliminate the reactive oxygen species.

As stated above, in Phillips, immediately after forming in the energy centers of the mitochondria free radicals are subject to attack by the fuel gas. It is well known in the art that the hydroxyl radical reacts with H_2. (i.e., $2OH^{\cdot} + H_2 \rightarrow 2H_2O$) These radicals are thus rendered harmless, and cell structures, DNA, fatty acids, etc will not be subject to oxidation, with the ensuing cascade of further free radical formation and destruction.

With respect to claims 61 and 70, the examiner asserted that the invention is inoperable because the applicant is asserting presentation of the same gas composition in both hyperbaric and hypobaric conditions, and the gas composition cannot be delivered at the same instant in time under two completely opposite conditions.

Claim 70 has been amended to depend from claim 8. Withdrawal of the rejection is respectfully requested.

In view of that the Federal Circuit has stated, "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980), the examiner's rejection is not proper.

III. Claim Rejections - 35 U.S.C. 112 - Written Description

The claims 8-13, 15, 17, 29, 32, 58-63, 68 and 70 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the enablement requirement and the best mode requirement.

1. The examiner improperly asserted that the written description is devoid of these method steps being exclusively performed on land.

Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency

of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Here, the specification explicitly or inherently disclose the present invention which can be performed on land or under the water. With respect to the embodiment performed on land, Applicant also explicitly discloses it in the specification and the figures. The applicant conveys with reasonable clarity to those skilled in the art that he was in possession of the invention. The above claims merely recite the feature *explicitly* described in the specification and the drawings. Where there are more than one embodiments, the applicant may freely claim one of the embodiments. That is, even if the present invention can be performed on land or under the water, there is nothing wrong in claim 8. Nonetheless, the examiner improperly asserted that the specification did not disclose that the claimed methods are exclusively performed on land. The examiner confused the written description requirement issue with the obviousness issue. If the examiner wants to use the reference showing the method under the sea, the examiner should argue that the claimed method is obvious from the reference disclosing the method under the sea on a proper ground. Where the specification and the figures disclose the methods performed on land, the examiner's rejection is unreasonable. If the examiner still believes that the claims fail to comply with the written description requirement, the applicant respectfully requests the examiner to provide why the methods in the specification and the figures do not show that the claimed methods are performed on land. Also, it should be noted that, *even* where the specification discloses two embodiments one of which is performed under the

sea and the other of which is performed on land, the applicant freely claims one of the embodiments. The patent law or rule does not prohibit the applicant from claiming each embodiment in each different claim.

Since the specification including the figures clearly shows that the methods are performed on land, the written description is met.

2. The examiner also improperly asserted that the written description is devoid of any disclosure how providing gaseous materials that either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect issue.

It looks like that the examiner's rejection is based on Phillips. As stated above, Phillips does not represent all the reactions associated with the reactive oxygen species, and the claimed methods in the present invention are performed in a different condition because the gas, unlike Phillips, is *intentionally supplemented with a fuel gas*. It is well known in the art that the different condition may make the different result. Also, it is well known in the art that the reactive oxygen species can react with compounds such as methane, ethane, and hydrogen. The specification explicitly states from page 5, line 18 to page 6, lines 1-5 that "the present invention is a method to produce a beneficial effect such as that seen with low-calorie diets in animals, by neutralizing reactive oxygen species to reduce ham to the body. The present method,..., involves the maintenance of concentrations in the body of one or more compounds whose purpose is to combine with and overwhelm the reactive oxygen species, and to remove them as they are produced to greatly lower

the levels of these reactive oxygen species." This disclosure and the other detailed description convey to the artisan that the inventor had possession of the claimed subject matter. Also, irrespective of whether the fuel gas assists in the creation of oxygen free radicals, the intake of the gas intentionally supplemented with the fuel gas removes the reactive oxygen species before the reactive species undergo reactions with compounds in the body.

Furthermore, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. Here, the examiner's rejection is based at most on Phillips which has a different reaction condition, that is does not show the reaction where the animal intakes the gas intentionally supplemented with fuel gas and does not show that the reactive oxygen species cannot be removed before the reactive oxygen species undergo the reactions shown in Phillips.

IV. Claim Rejections - 35 U.S.C. 112 - Enablement

The claims 8-13, 15, 17, 29, 32, 58-63, 68 and 70 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The examiner also improperly asserted that the written description is devoid of any disclosure

to enable one to protect tissue from oxygen free radicals by providing gaseous materials that actually either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect issue.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The specification explicitly states from page 5, line 18 to page 6, line 5 that "the present invention is a method to produce a beneficial effect such as that seen with low-calorie diets in animals, by neutralizing reactive oxygen species to reduce ham to the body. The present method,..., involves the maintenance of concentrations in the body of one or more compounds whose purpose is to combine with and overwhelm the reactive oxygen species, and to remove them as they are produced to greatly lower the levels of these reactive oxygen species." This object is achieved by the claimed methods. The claimed methods are directed to deliver the compounds to the body. It is clear that one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The

examiner's reasoning of the enablement rejection is not related to "undue experiment" test, and, if related, it is not clear why undue experiments are required to make or use the present invention.

V. Claim Rejections - 35 U.S.C. 112 - Best Mode

The claims 8-13, 15, 17, 29, 32, 58-63, 68 and 70 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the best mode requirement.

The examiner improperly asserted that the written description is devoid of any disclosure to a best mode as to how one protects tissue from oxygen free radicals by providing gaseous materials that actually either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect issue.

The examiner's rejection is not related to the best mode requirement. Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention. This is a subjective inquiry which focuses on the inventor's state of mind at the time of filing. Second, if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

MPEP 2165.03 states that:

"The examiner should assume that the best mode is disclosed in the application, unless

evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings."

Here, no evidence is found inconsistent with that assumption. Nonetheless, the examiner merely asserts that the present application fails to comply with the best mode requirement based on irrelevant facts. If the examiner has any evidence to show that, at the time the application was filed, the inventor possessed a best mode for practicing the invention which was not disclosed in the specification, and the written description did not disclose the best mode, the rejection should be based on the evidence. The examiner's rejection disregards the two-prong inquiry and is not proper.

The examiner used the same assumption that the present invention is wholly inoperative in rejecting the claims under 35 U.S.C. 101, the written description requirement, the enablement requirement, and the best mode requirement without considering each test for each requirement. The examiner's reasoning is not clear. As stated above, the examiner's reasoning for the utility requirement is valid only where the invention is wholly inoperative. If the examiner is sure that the invention is wholly inoperative, how does the examiner reject claims on the written description requirement and the enablement requirement based on the same reasoning used for the utility requirement rejection? Furthermore, the examiner must always remember to use the perspective of **one of ordinary skill in the art**. Claims and disclosures are not to be evaluated in a vacuum.

Reconsideration of the rejections under 35 U.S.C. 112 is respectfully requested.

VI. Claim Rejections - 35 U.S.C. 102

Claims 8-9, 15 and 17 stand rejected under 35 U.S.C. 102(a) as being anticipated by Stamler (U.S. Pat. No. 6,314,956).

"Office personnel must rely on the applicant's disclosure to properly determine the meaning of terms used in the claims. *Markman v. Westview Instruments*, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (*en banc*), *aff'd*, U.S., 116 S. Ct. 1384 (1996). An applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings.")." See MPEP §2106.

Here, the specification explicitly defines the term "fuel gas compound" as "any chemical compound which in pure form is a gas and which in pure form can be readily oxidized by oxygen for heat production. (See page 10, lines 15-17.)

The examiner asserted that the ethyl nitrite is included in the term "fuel gas compound" in claim 8.

The examiner's assertion is not proper for the following reasons.

First, ethyl nitrite in pure form is not a gas, but a liquid.

Second, the compounds including ethyl nitrite disclosed in Stamler do not react with reactive oxygen species.

Stamler discloses the use of the compounds, specifically ethyl nitrite, having a NO group and having a hypoxemia relieving and a smooth muscle constriction relieving effect with the NO group being bound in the compound. Free NO can aggravate the injury by reacting with oxygen free radicals to form toxic products of reaction, but the compounds with NO group administered in Stamler do not react with oxygen free radicals (column 3, lines 38- 43). That is, Stamler does not disclose the "fuel gas."

Since the compounds disclosed in Stamler are not "fuel gas" and do not react with reactive oxygen species within the animal, the claim 8 is not anticipated by Stamler.

The dependent claims 9, 15 and 17 are not anticipated by Stamler, either.

VII. Claim Rejections - 35 U.S.C. 103

Claim 32 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler.

Claims 10, 13 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler in view of Delauze (WO 96/06771).

Claims 11-12 and 58-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler and Delauze as applied to claim 10, and further in view of Gardner et al.

Claims 62 and 65-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler as applied to claim 8, and further in view of Scherer et al.

Claim 68 stands further rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler

and Scherer as applied to claims 65 and 67, and further in view of Delauze.

Claim 70 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler and Delauze as applied to claim 61, and further in view of Kotliar.

1. Claims 10-13, 32, 58-62 and 70

The claims 10-13, 32, and 58-62 are not obvious for the following reasons.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

First, as stated above, the examiner did not show that the prior art teach or suggest all the claim limitations because the "fuel gas" which reacts with reactive oxygen species" is not taught or suggested in Stamler combined with the cited references.

Stamler discloses the use of the compounds having a NO group and having a hypoxemia relieving and a smooth muscle constriction relieving effect with the NO group being bound in the compound (see column 3, lines 51-64). Free NO can aggravate the injury by reacting with oxygen free radicals to form toxic products of reaction but the compounds with a NO group administered in Stamler do not react with oxygen free radicals (column 3, lines 38- 43).

That is, the compounds in Stamler do not aggregate the injury because the NO group in the

compounds of Stamler does not react with free radical oxygen. In other words, the compounds of Stamler do not remove free radical oxygen or reactive oxygen species.

Nonetheless, the examiner improperly asserted that Stamler discloses the use of hydrocarbon-based free radical reducing gases.

Second, the teaching in Stamler combined with the other references teaches away from the claimed invention.

As stated above, Stamler teaches the compounds which not react with reactive oxygen species. On the other hand, the present invention is directed to remove reactive oxygen species.

The Supreme Court held that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Therefore, the examiner's rejection should be withdrawn.

Third, with respect to claims 13 and 62, the proposed modification renders Stamler unsatisfactory for its intended purpose.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed

modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

If the compounds of Stamler are replaced with hydrogen or acetylene as suggested by the examiner, Stamler cannot achieve its intended purpose. The purpose of Stamler is to react the compound with cysteine in hemoglobin and/or dissolves in blood by delivering the compound into the lungs without reaction with reactive oxygen species. If the compounds of Stamler are replaced with hydrogen or acetylene, the intended purpose cannot be achieved. Therefore, there is no suggestion or motivation to make the proposed modification.

Accordingly, the examiner failed to establish a prima facie case of obviousness.

Fourth, hydrogen is not equivalent to the compounds of Stamler.

Regarding claim 13, the examiner merely asserted that the suggestion/motivation for doing so would have been because such are interchangeable equivalents.

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

It is not clear for which purpose hydrogen and the compounds of Stamler are equivalents. Applicant respectfully requests the examiner to clarify this issue. It should be noted that the equivalency cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. Neither Stamler nor Delauze nor the knowledge in the art recognizes such equivalency.

Fifth, the cited references are nonanalogous art.

To rely on a reference under 35 U.S.C. 103, it must be analogous prior art.

"In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

The examiner asserted that all the cited references are analogous art.

First, as a first test, the examiner must determine the references are in the field of applicant's endeavor.

The examiner asserted that the present invention and all the cited references are related to respiratory art. This examiner's definition of "analogous art" is too broad for analogous art determination. The field of Stamler is pulmonary disorder, the field of Delauze is underwater diving apparatus, and the field of Scherer is a cardiac output test. Particularly, Delauze and the other cited references are not in the same field.

Second, all the references are not reasonably pertinent to the particular problem with which the inventor was concerned. That is, all the cited references are not reasonably pertinent to the system for providing protection from reactive oxygen species.

For more detailed reasoning, please consider the following points.

With respect to Delauze et al., the Delauze cannot be considered in determining obviousness issue because Delauze et al. is not analogous art.

The examiner classified claims 1-32, 52 and 58-60 in class 514, subclass 789 in the Office action (Paper No. 4), while the Delauze invention is classified in class128, subclass 201.7 (and its field of search is class 128, subclasses 200.24, 201.21, 201.27, 201.28, and 204.26). Class 514 relates to drug, bio-effecting and body treating compositions. (It should be noted that the examiner does intentionally avoid classifying claims 1-32, 52 and 58-60 in class 128 for the restriction purpose, while classifying claims 33-37, 43-51, 53, 54-57 in class 128. Therefore, the examiner admits that claims 1-32 and 58-61 relates to drug, bio-effecting and body treating compositions. That is, as the examiner asserted in the restriction requirement, the pertinent art of the present invention is the art *for protection from reactive oxygen species*. Even without the examiner's classification, the present invention is not from the Delauze's field of endeavor. As stated in the specification, the prior art uses the ingestion of scavenging compounds for providing protection from reactive oxygen species (page 2, lines 8-13). This fact shows that the method for protection from reactive oxygen species is not inherently within the respiratory art. It is clear that the Delauze invention is not from the same field of endeavor. Alternatively or in addition, the Delauze et al. is in the field of the water diving rather than a respiratory art. (See page 1, lines 7-9 in Delauze et al: The technical sector of the invention is the domain of industrial underwater diving for operations at medium and great depth.)

While Patent Office classification of references and the cross-references in the official search notes are some evidence of "nonanalogy" or "analogy" respectively, the court has found "the similarities and differences in structure and function of the inventions to carry far greater weight." In re Ellis, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973) (The structural similarities and functional overlap between the structural gratings shown by one reference and the shoe scrapers of

the type shown by another reference were readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant's invention dealt (pedestrian floor gratings).). That is, in In re Ellis, the Court held that even if there is evidence of Patent Office classification, the similarities and differences in structure and function of the inventions must be considered for determining whether the reference invention is pertinent to the arts to with which the present invention dealt.

Thus, under In re Ellis, we have to still ascertain if the art is reasonably pertinent to the particular problem with which the inventor is involved.

Here, Delauze et al.'s disclosure has a different purpose and relates to a different problem (i.e., making dives from installations ensuring the immersion and pressurization of divers down to a certain depth beyond 50 meters, and allowing the divers to carry out a given work safely and efficiently down to at least 650 meters (page 1, lines 10-18)). The person of ordinary skill would not reasonably be expected to see the Delauze et al. for a solution to the problem (i.e., for providing protection from reactive oxygen species).

Therefore, Delauze et al. is nonanalogous art.

With Scherer et al., the Scherer invention is for determining cardiac output for an individual from CO_2 gas expirograms. (col. 1, lines 10-15). On the other hand, the present invention and Delauze et al. do not relate to the cardiac output. Thus, the art is not from the same field of endeavor. Moreover, there are no similarities in structure and function between Scherer et al. and Delauze et al. (and/or the present invention). Thus, a reference is not reasonably pertinent. Likewise, Kotliar cannot be considered as analogous art.

For at least one of the reasons stated above, withdrawal of the rejections of claims 10-13, 32, 58-62 and 70 are respectfully requested.

2. Claims 65-68

For the reasons stated above, the claims 65-68 are not obvious over the prior art because the examiner failed to establish a prima facie case of obviousness. Some of the reasoning is repeated below.

First, the proposed modification renders Stamler unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

If the compounds of Stamler are replaced with acetylene, Stamler cannot achieve its intended purpose. The purpose of Stamler is to react the compound with cysteine in hemoglobin and/or dissolves in blood by delivering the compound into the lungs without reaction with reactive oxygen species. If the compounds of Stamler are replaced with acetylene, the intended purpose cannot be achieved. Therefore, there is no suggestion or motivation to make the proposed modification.

Accordingly, the examiner failed to establish a prima facie case of obviousness.

Second, the teaching in Stamler combined with the other cited references teaches away from the claimed invention.

As stated above, Stamler teaches the compounds which not react with reactive oxygen species. On the other hand, the present invention is directed to remove reactive oxygen species.

The Supreme Court held that a prior art reference must be considered in its entirety, i.e., as

a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Therefore, the examiner's rejection should be withdrawn.

Third, acetylene is not equivalent to the compounds of Stamler.

Regarding claim 13, the examiner merely asserted that the suggestion/motivation for doing so would have been because such are interchangeable equivalents.

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

It is not clear for which purpose hydrogen and the compounds of Stamler are equivalents. Applicant respectfully requests the examiner to clarify this issue. It should be noted that the equivalency cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. Neither Stamler nor Delauze nor the knowledge in the art recognizes such equivalency.

Fourth, the cited references are nonanalogous art for the same reasons stated above.

No fee is incurred by this Amendment. Should other fees be incurred, the Commissioner is authorized to charge Deposit Account No. 02-4943 of Applicant's undersigned attorney in the amount of such fees. Should questions remain unresolved, the Examiner is requested to telephone the Applicant's attorney.

Should a Petition for extension of time be required with the filing of this response, the Commissioner is kindly requested to treat this paragraph as such a request and is authorized to charge Deposit Account No. 02-4943 of Applicant's undersigned attorney in the amount of the incurred fee if a check of the requisite amount is not enclosed.

In view of the above, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections and objections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

Respectfully submitted,

Robert E. Bushnell
Attorney for Applicant
Reg. No.: 27,774

1522 K Street, N.W.
Washington, D.C. 20005
(202)408-9040
Folio: P56156
Date: 2/25/04
I.D.: REB/JHP